

REMARKS

Reconsideration of this application is respectfully requested.

I. Status of the Claims

Claims 23-33, 35-47, and 49-58 are pending, with claims 51-58 indicated as allowed. *See* Office Action mailed June 12, 2003. Thus, claims 23-33, 35-47, and 49-50 remain pending and rejected.

II. Rejections under 35 U.S.C. § 102

A. Rejection of Claims Under 35 U.S.C. § 102(e) Over Merril

Claims 23-25, 29, 30, 33-39, 43-44, 47, 49, and 50 were rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by Merril et al., U.S. Patent No. 5,688,501 ("Merril"). Office Action at page 2. Applicants respectfully traverse this rejection.

As described in more detail below, Merril fails to teach the claimed invention because: (1) Merril does not teach virulent bacteriophage having a broad host range; (2) Merril does not teach a virulent bacteriophage preparation selected based on the bacteriophage's ability to kill bacteria; and (3) Merril does not teach a virulent bacteriophage preparation comprising two or more bacteriophage strains.

This is significant, as under 35 U.S.C. § 102, a claim is anticipated when each and every element set forth in the claim is found, either expressly or inherently, in a single prior art reference. *Verdegaal Brothers, Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). If the reference fails to teach or suggest even one limitation of the claimed invention, then the claim is not anticipated. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984).

**1. Merril Does not Teach Virulent
Bacteriophage Having a Broad Host Range**

The claims were rejected on the grounds that Merril discloses a bacteriophage capable of killing bacteria from a variety of different hosts. Specifically, the Examiner asserted: “clearly the lambda phage of Merril et al. are able to kill bacteria from a variety of different hosts.” *See* Office Action, page 3, item 11. In contrast to the Examiner’s assertion, the evidence and explanation of record does not demonstrate that Merril discloses bacteriophage having broad host range, as required by Applicants’ claims.

The Examiner cited several passages from Merril (e.g. col. 3, lines 45-49; col. 4, lines 45-49; col. 12, lines 4-6; and claims 1, 9, 12-13, and 15-16) that allegedly disclose a bacteriophage having a wide host range. The cited passages of Merril neither disclose nor describe a bacteriophage having a wide host range.

In fact, Merril teaches a bacteriophage preparation that is *specific for a particular bacterial strain*. Specifically, Merril teach that the disclosed bacteriophage “are specific for each of the bacterial strain of interest.” *See* col. 6, lines 63-67. Furthermore, Merril teaches that: “a full array of anti-HDS selected and/or anti-HDS engineered bacteriophage is developed for virtually all the bacterial (and other applicable) pathogens.” *See* col. 6, line 67, through col. 7, line 5. Therefore, Merril does not disclose a bacteriophage having a broad host range.

To further support the assertion that Merril allegedly teaches bacteriophage having a wide host range, the Examiner asserts that: “Merril utilized lambda coliphages . . . which would specifically interact with multiple strains of *E. coli* based upon the lambda receptor being present in *E. coli*.” *See* Office Action, page 3, item 13.

Contrary to the Examiner’s assertion, Merril does not disclose lambda coliphage interacting with multiple strains of *E. coli*. In fact, Merril disclose that the *E. coli* strain was selected specifically for its known ability to be lysed by the genetically-engineered coliphage. *See* col. 14, lines 48-49.

Accordingly, Merril does not teach virulent bacteriophage having a broad host range, as required by the claimed invention.

2. **Merril Teaches a Bacteriophage Selected Based on Long Circulation Times, in Contrast to Applicants' Claimed Invention, Requiring Selection of a Virulent Bacteriophage Preparation Based on the Bacteriophage's Ability to Kill Bacteria**

Merril does not teach a virulent bacteriophage preparation selected based on the bacteriophage's ability to kill bacteria, as required by the claimed invention. Rather, Merril disclose a method for producing bacteriophage that have increased resistance to inactivation by the treated animal's host defense system.

Merril teaches methods of isolating bacteriophage that are able to survive longer in the host body as compared to the wild-type phage. *See* col. 5, lines 38-45. The methods comprise serial passage or genetic engineering, such as genetically engineering a phage "to express molecules on its surface coat, where [the] molecules antagonize, inactivate, or in some other manner impede those actions of the HDS that would otherwise reduce the viability of the administered phages." *See* col. 5, lines 50-57. In particular, Merril disclose an anti-HDS modified bacteriophage with "a half-life 15 % greater than the half-life of the original wild-type phage from which it was derived." *See* col. 5, lines 10-12. According to Merril, "[a] 15 % longer half-life indicates a successful delay of inactivation by the HDS." *See* col. 5, lines 17-19.

Merril does not teach or suggest bacteriophage having increased capabilities of killing bacteria, as required by the claimed invention. This is because bacteriophage having a prolonged circulation time and viability, such as those taught by Merril, may be *less* virulent and therefore *ineffective* as a treatment.

3. In Contrast to Applicants' Claimed Invention, Merril Does not Teach a Virulent Bacteriophage Preparation Comprising Two or More Bacteriophage Strains

The Examiner asserted that Merril teaches a composition comprising two or more bacteriophage strains. In contrast to the Examiner's assertion, the evidence and explanation of record do not suggest that Merril teach a bacteriophage composition comprising two or more bacteriophage strains. None of the Merril passages cited by the Examiner teach a composition comprising two or more bacteriophage strains (*see* Office Action, page 4, item 15).

Because Merril does not anticipate the claimed invention, withdrawal of this ground for rejection is respectfully requested.

B. Rejection of Claims Under 35 U.S.C. § 102(b) Over Norris

Claims 23, 24, 33, 37, 38, and 47 were rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Norris, U.S. Patent No. 4,957,686 ("Norris"). Applicants respectfully traverse this ground for rejection.

The Examiner alleged that the bacteriophage preparation of Norris has a wide host range: "the bacteriophage that would infect one strain of *S. sanguis*, would also infect another strain of *S. sanguis* with the same or equivalent receptor." *See* Office Action, page 5, item 18.

In contrast to the Examiner's assertion, the evidence and explanation of record do not suggest that Norris teaches a bacteriophage capable of infecting more than one strain of *S. sanguis*. Specifically, Norris teaches that: "[e]ach phage is specific to one kind of bacteria and does not attack other cells, bacteria, or other." *See* col. 3, lines 28-30. Furthermore, Norris teaches that the "phages contact other bacteria of the kind to which they are specific and destroy these...." *See* col. 3, lines 36-40.

Accordingly, because Norris does not disclose or describe a bacteriophage preparation having a wide host range, Norris does not anticipate the claimed invention. Therefore, withdrawal of the rejection is courteously requested.

III. Rejections Under 35 U.S.C. § 103

A. Rejection Over Merril in View of Denney

Claims 26 and 40 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Merril in view of Denney, U.S. Patent No. 3,793,151 (“Denney”). Applicants respectfully traverse this ground for rejection.

Merril is deficient for the reasons as discussed above, and Denney does not remedy the deficiencies of Merril. As a *prima facie* case of obviousness requires the combination of references to teach or suggest every aspect of the claimed invention (see MPEP 2143.03), the combination of cited references does not render the claimed invention obvious. Accordingly, Applicants respectfully request withdrawal of the rejection.

B. Rejection Over Merril in View of He

Claims 27 and 41 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Merril in view of He et al., “Bacteriophage Lytic Patterns from the Identification of *Salmonellae*, *Shigellae*, *Escherichia coli*, *Citrobacter freundii*, and *Enterococcus cloacae*,” *J. of Clin. Microbiol.*, 30(3):590-594 (1992) (“He”). Applicants respectfully traverse this ground for rejection.

Merril is deficient for the reasons discussed above, and He does not remedy the deficiencies of Merril. Because the combination of cited references does not render the claimed invention obvious, Applicants respectfully request withdrawal of the rejection.

C. Rejection Over Merril in View of Sekaninova et al.

Claims 28 and 42 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Merril in view of Sekaninova et al., *J. of Public Health*, 3(2):80-83 (1995) (“Sekaninova”). Applicants respectfully traverse this ground for rejection.

Merril is deficient for the reasons discussed above, and Sekaninova does not remedy the deficiencies of Merril. Because the combination of cited references does not render the claimed invention obvious, Applicants respectfully request withdrawal of the rejection.

D. Rejection Over Merril in View of Bar-Shalom et al.

Claims 31 and 45 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Merril in view of Bar-Shalom et al., U.S. Patent No. 5,213,808 (“Bar-Shalom”). Applicants respectfully traverse this ground for rejection.

Merril is deficient for the reasons discussed above, and Bar-Shalom does not remedy the deficiencies of Merril. Because the combination of cited references does not render the claimed invention obvious, Applicants respectfully request withdrawal of the rejection.

E. Rejection Over Merril in View of Tomalia et al.

Claim 45 was rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Merril in view of Tomalia et al., U.S. Patent No. 5,714,166 (“Tomalia”). Applicants respectfully traverse this ground for rejection.

Merril is deficient for the reasons discussed above, and Tomalia does not remedy the deficiencies of Merril. Because the combination of cited references does not render the claimed invention obvious, Applicants respectfully request withdrawal of the rejection.

CONCLUSION

In view of the foregoing arguments, the claimed invention is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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